(e) You must tell the employee that additional tests of the specimen *e.g.*, DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

- (a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.
- (b) You must check the "dilute" box (Step 6) on Copy 2 of the CCF.
- (c) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under §40.197, to include the requirement for an immediate recollection under direct observation if the creatinine concentration of a negative-dilute specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL.
- (d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:
- (1) Review the CCF to ensure that there is documentation that the recollection was directly observed.
- (2) If the CCF documentation shows that the recollection was directly observed as required, report this result to the DER as a negative-dilute result.
- (3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35971, June 25, 2008]

§ 40.157 [Reserved]

§ 40.159 What does the MRO do when a drug test result is invalid?

- (a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:
- (1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not contact you

- as required by §§40.91(e) and 40.96(c), you must contact the laboratory.
- (2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.
- (3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.
- (4) If the employee gives an explanation that is acceptable, you must:
- (i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection not required" on the "Remarks" line.
- (ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.*, pre-employment, return-to-duty, or follow-up tests).
- (iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen, as the MRO, you must follow the procedures outlined at §40.160 for determining if there is clinical evidence that the individual is an illicit drug user.
- (5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:
- (i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection required" on the "Remarks" line.
- (ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.
- (iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.